Test report R-EL-280-0808-01A

SAFETY

Issued to:	**AXEL s.r.l.** Via F. Matteucci, 11 50041 Calenzano (FI)
Item under test	Acupunture pen Brand: **AXEL s.r.l.** Model: **PAIN·AWAY** Serial n.: XXXXXX
Reference standards	**CEI EN 60601-1 2ª edizione**
Type of test	**Safety**
Result	**PASS**

Revision	**1a**	Dated	**21/08/08**
Draft:	**Ing. L. Spinelli**	Approval:	**Ing. L. Spinelli**
Stamp			

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CERMET SISTEMA DI GESTIONE CERTIFICATO
REG. N. 5315
UNI EN ISO 9001:2000

INDEX

1. SCOPE

This document has been drafted with the scope of documenting the tests executed to verify the conformity of the device with the safety prescriptions of reference documents.

The analysis conducted concerned the examination of the technical documentation referring to the device, the carrying out of a visual inspection in the aim of determining the applicable standards and, if requested,the performing of tests on the device. The tests has been executed in the conditions and with the methodologies defined in the applicable standards and their results are riported in the check lists inside paragraph 4.

This document must be inserted inside Technical File and it will be the technical referece regarding the observance of the prescriptions deriving from the applicable norms.

The analysis carried out concerns the device set up in conditions suitable for delivery to the customer: in the event of modifications being carried out that in any way alter the features of the insulations, the clearances and creepage distances, the characteristics of infiammability or of the materials and components realizing the insulations, it will be necessary to repeat the tests in order to validate the modifications made.

The report contains the results of the analysis executed on the described device and it doesn't entitle to affix any type of mark. To do that it's required the conformity declaration of the constructor. To affix the name of the laoratory in connection with the use, the promotion or other of the described device will only be admitted against explicit written authorisation.

The results of the measurements recorded in this document refer exclusively to the example examined and in the conditions of the measurements specified. Any extension of the results to other examples or in other measuring conditions shall not enter within the scope of this document.

2. IDENTIFICATION AND FETURES OF THE DEVICE

- Type of device:	**Agopunture pen**
- Manufacturer	**AXEL s.r.l.**
- Type:	**PAIN·AWAY**
- Serial number:	xxxxx
- Rated voltage:	**Internal piezoelectric source**
- Mains connection:	**--**
- Type of installation:	**Portable**
- Protection against indirect contacts:	**Class II**
- Applied parts:	**Type BF**
- Date of receipt:	**05/06/2008**

- Photograph of the device under test

3. REFERENCE DOCUMENTS

The considerations contained in this document are aimed at verifying the observance of the provisions deriving from the following Community Directives:

- Medical Equipment Directive CEE 93/42, in Italy with Legislative Decree 46/97

Observance of the above-mentioned directives has been obtained by making reference wherever applicable, to the following standards:

- ***CEI EN 60601-1*** *versions* ***A11, A12, A13*** ”Medical electrical equipment. Part 1: General requirements for safety” (1998-12) .

- CEI EN 60601-2-10 “Medical electrical equipment. Particular standard for neuromuscolar stimulator ” 2001-11)

4. CONFORMITY CHECK

It has been verified the respect of safety requirements of the norms EN 60601-1 and EN 60601-2-10 by the carrying out of a visual inspection and by tests applicable to the features of the considered device. Such an operation has involved a check of the articles from n. 6 to n. 59.4 includes of the norm.

The evidence and the results of the executed tests are riported in the following table, where it's indicated: on the first column, the reference to the article of the norm; in the second one, the prescription of the same; in the third one, the survey resultants from observation and/or from the measure/es executed; in the fourth one; the applicability of the norm's article or the result about the respect of applicable prescriptions. Abbreviations have the following meaning:

C = Conform; **NA** = Not applicable; **NC** = Not conform; **TE** = To evaluate

In paragraph 5 there are the test conditions and in paragraph 6 the conclusions about the respect of the prescriptions of the applicable documents so that they can be clear to Your Society the actions to undertake for the resolution of not conformity, if emerged, or to attest the conformity of the device.

ref. Norm	*Prescription*	*Observed*	*Outcome*
	General prescriptions (art. 3)		
3.1	Transport, storage, operative becoming and maintenance	There is'nt any possible danger	C
3.4	Devices and their parts made with materials or methods differnt from the specifications: equivalent safety level	--	NA
	General prescriptions relevant to tests (art. 3)		
4.5	Temperature, humidity and atmospheric pressure of test environment: - temperature - humidity - atmospheric pressure	 18°C÷ 40°C 45% ÷ 75% 860hPa ÷ 1060hPa	C
	General prescriptions relevant to tests (art. 5)		
5.1	Type of classification	Device with internal source (piezoelectric)	C
5.2	Classification on the basis of the protection against direct and indirect contacts	Device Type BF	C
5.3	Protection degree against water ingress	IP20	C
5.4	On the basis of sterilization or disinfection	Disinfection and cleaning	C
5.5	On the basis of safety level of employment in the presence of an anaesthetic inflammable mixture with air, oxigen or nitrous protoxide	Not suitable for use in the presence of an anaesthetic inflammable mixture	C
5.6	On the basis of employment conditions	Continuos operation	C
	Identification, rating and other indications, annexed documentation (art. 6)		
6.1	Visual inspection of: - rating and other indications on the principal part of devices or parts of devices.	Manufacturer, model nd classification data written on the enclosure	C
6.2	- Indications inside devices or parts of devices	No need of this symbols	NA
6.3	- IIndication of command devices and instruments	No need of this symbols	NA
6.4	- Symbols	Symbols correct; class BF	C
6.5	- Colours of the insulation in the conductors	Not applicable prescriptions	C
6.6	- Identification of the bottled gas for medical use and of its connections	---	NA
6.7	- Dial lamps and push-buttons	Not applicable prescriptions; symbol used 	C
6.8	- Annexed documentation: User guide	Manual complete	C

ref. Norm	*Prescription*	*Observed*	*Outcome*
	Necessary information: a) general informations; b) manufacturer's responsability; c) Parts of I/O signal; d) cleaning, disinfection and sterilization of the parts in contact with the patient; e) additional electric supply f) batteries removal; g) rechargeable batteries; h) battery charger supply; i) environmental protection.		
6.8.3	Technical description: a) Generality b) Fuse and other parts substitution c) Circuit diagrams, list of component parts d) Limited environmental conditions for transport and stocking.	Manual complete	C
	Power input (art. 7)		
7	Measurement of device input: - supply voltage: -operation load/cycle: - measured value: - stated value: - obtained error: - admitted error limit:	No external supply	NA
	General prescription relevant to the classification (art. 14)		
14.1	Visual inspection of the prescription relevant to the classification:		
14.2	- devces class I		NA
14.3	- devices class II	Class II	C
14.4	- devices class I and II		NA
14.5	- devices with internal electric source		NA
14.6	- applied parts type B, BF, CF;	applied parts type BF	C
	Voltage and/or energy limitations (art. 15)		
15	b) residual voltage relief on the inlet: measured: prescribed: < 60V after 1s c) capacitors' energized parts or accessible after enclosures removal.	No inlet Voltage < 60V after cover removal	NA C
	Protection enclosures and doors (art. 16)		
16a	Visual inspection and tests of: -protection against contacts with energized parts and parts that can become energized in case of fbasicl insulation fault	Control executed with jointed and rigid finger test probes, test inlet and test hook.	C
16b	-enclosures opening	Control with test rod	C
16c	- conductor parts of command mechanisms	Insulated	NA
16d	-internal parts at voltage higher than 25Va.c. and 60V c.c not disconnected from mains supply	No connection with power supply	NA
16e	-enclosures removal	Removable only with distruction;	C
16f	-regualtion opening	Not present	NA
	Separation (art. 17)		
17a	Visual inspection of the prescriptions relevant to the separation between: -applied parts and energized parts	Applied parts separated in respect to main parts (no main connection)	C
17c	-applied parts not connected to parts that are'nt protect with earthing	Maniple is insulated	C
17d	-Flexible shafting to hold in hand and accessible metal parts	Maniple with insulated handle;	C

ref. Norm	*Prescription*	*Observed*	*Outcome*
17g	-Accessible parts and energized parts;	see dispersion currents measurement art.19	C
17h	- separation of applied parts proof defibrillator: tests	--	NA
Protective earthing, functional earthing and equalization of potential (art. 18)- Wiring terminals and connections (art. 58)			
18a	Visual inspections of: -accessible parts earthing for class I devices	 Class II device	NA
18b	-earthing	--	NA
18e	-connection of equipotential conductor	--	NA
18f	-Earth circuit impedance measurement: measured value: Limit value:	--	NA
18g	-Other earth connections impedance measurements measured value: Limit value:	--	NA
18k	Visual inspection of: - earth functional wiring terminals	--	NA
18i	- third conductor of supply cord for class II devices	--	NA
58	Visual inspection of wiring terminals, connections and blocking equipment.	--	NA
Mechanical strenght (art. 21) and fire prevention (art. 43)			
21	Strenght and rigidity enclosures test: -force towards the inside 45N -three strokes, energy 0,5J -transport handles test; wight test:	No deformations No damages --	C
21.3	Parts to support or to immobilize the patient; tests: -patient supports: nominal load: safety factor; test weight: -feetrest and chairs: test weight:	--	NA
21.5	Devices or parts to hold in hand: falling height: 1m	Device fallen from 1m	C
21.6	Hard treatement resistance of transportable or movable devices	--	NA
43 43.1	Fire prevention Strenght and rigidity	Adequate enclosures	C
43.2	Oxigen enriched atmospheres	--	NA
Parts in movement (art. 22)			
22.2	Visual inspection of: -exposed parts in movement	 No part in movement, except for the push button and internal spring	C
22.3	-cables, chains and belts	--	NA
22.4	-movements with continous activation	--	NA
22.6	-parts subject to mechanical wear	--	NA
22.7	-mechanical movements interruption	--	NA
Surfaces, edges and borders (art. 23)			
23	Visual inspection to verify the absence of rough surfaces, edges and borders	Rounded edges and abscence of marks	C
Stability in normal use (art. 24)			
24.1	Stable device if inclined of 10°	Portable	NA
24.3	Unstable device if inclined of 10°; verification additional prescriptions	--	NA
24.6	Handles	--	NA
Outside projected parts (art. 25)			
25.1	Visual inspection of equipment for: -outside projected parts protection	 --	NA

ref. Norm	*Prescription*	*Observed*	*Outcome*
25.2	-electronic tubes	--	NA
	Hanging masses (art. 28)		
28.3	Visual inspection of equipment for: -sospension systems with safety equipment	Not present	NA
28.4	-metal sospension systems without safety equipment	Not present	NA
	X-Rays (art. 29)		
29.2	Measurement of dose intensity of X-rays: limit value: 130nc/kg (0,5mR) in one hour	--	NA
	Tanks and parts in pressure (art. 45)		
45.2	Hydraulic test pressure resistant tanks working pressure:	Not in pressure	NA
45.3	Maximum admissible pressure for the parts	Not in pressure	NA
45.7	Safety valves		NA
	Excessive temperatures (art. 42)		
42	Temperature measurement in normal operating conditions;	Temperatures measured inside limits See details in par. 5.1	C
	Interruzione dell'alimentazione elettrica (art. 49)		
49.1	Visual inspection: -Automatic reset of temperature limiters and maximum current protectve devices	No thermal limiter	NA
49.2	-supply interruption and re-establishment	Internal energy	NA
49.3	-mechanical constraints on the patient	--	NA
	Operating data precision (art. 50)		
50.1	Regulation of output from minimu to maximum at steps or continuously	Continuously	C
50.2	Maximum value of output less than +30% of declared values	Rated 15kV with no load, 2,6mJ on 2000Ω Measured: 9,44kV with no load, 1875kV with 2000 Ω	C
	Protection against dangerous supplies (art. 51)		
51.1	Intentional exceeding the safety limits	No limits above which safety levels are overcome	NA
51.2	Safety parameters indication	Output levels are not dangerous	NA
51.3	Components reliability	No prescriptions	--
51.4	Casual selection of excessive output value	No selection	NA
51.5	Wrong output data	No prescriptions	--
51.101	Supply voltage which varies by ±10% doesn't change output by more than 10%	No output variation	C
51.102	Appliances with output more than 10mA or 10Veff programmed so that output is not activated if controls are not at the minimum value	Only one possible value	NA
51.103	Appliances with output more than 10mA or 10Veff on a load of 1000Ω have a yellow output signal	Only one pulse with button discharge	NA
51.104	Output current less than limits over a load of 500Ω	Max value 72mA, limit 100mA	C
	Abnormal operating and fault conditions (art. 52)		
52	Verification of danger absence in the following fault condtions (one at a time):	No abnormal condition	NA

ref. Norm	*Prescription*	*Observed*	*Outcome*
Permanent leakage currents and permanent auxiliary currents on patient at operating temperature (art.19)			
19.	Leakage currents measurement; test conditions: - measurements executed before and after conditioning in humid chamber (U.R. 95%, t=30°C, lenght 48h) - supply voltage: - in normal operating conditions (N.C.) and first fault conditions (S.F.C.) - with the device standing-by and operating - opened and closed switch	Results (mA): Test repeated in first fault conditions and after preconditioning in humid chamber. For details see test chart in par. 5.2	
	Measure type: - leakage current to earth:	--	NA
	- leakage current in the enclosure:	Less than limit	C
	- leakage current in the patient:	Less than limit	C
	- leakage current in the patient, mains on applied part:	Less than limit	C
	- Auxiliary leakage current in the patient:	--	NA
Applied voltage test at operating temperature and at cold (art.20)			
20	Applied voltage test; test conditions: - test executed before and after condiitoning in humid chamber (U.R. 95%, t=30°C, lenght 48h), after the reaching of thermic regime and at cold respectively. Parts: - A-a1: between energized parts and safety earthed accessible parts. - A-a2: between eenrgized parts and insulating enclosure with a metal foil - A-e: energized parts that are not signal input or output parts and signal input or output parts that are not earthed. - A-f mains conected parts at different polarity - B-a mains connected parts and applied part. - B-c applied parts and parts that are mains separate with only fundamental insulaiton. - B-d type F applied part and enclosure and signal I/O parts	See details in test chart in par. 5.3 -- -- ---- -- -- 5320V No surface or air flashovers except for stim signals	C
Overflowing, pouring, losses, humidity, liquids penetration, cleaness, sterilisation, disinfection and compatibility (art.44)			
44.2	Degree protection verification against: - overflowing: inclination 15° with 15% more of water in the tank	No water	NA
44.3	- pouring: pouring test with 200ml	No water	NA
44.4	- losses:	--	NA
44.5	- umidity:	48h; 30°C 95%	C
44.6	- liquid penetration:	--	NA
44.7	- cleaness, sterilization and disinfection:	dry cloth;	C
44.8	- compatibilty with substances used with the machine.	--	NA
Component parts and general installation (art.56)			

ref. Norm	*Prescription*	*Observed*	*Outcome*
56.1	Visual inspections and tests: - generalities:	Components used in rated conditions.	C
56.3	Connections: - connectors connection - conections between different parts - connections that are conductive to patient	 Not used	NA
56.4	Capacitors connections	Not used	NA
56.5	Protection devices	Not used	NA
56.6	Overload and thermic control devices	Not used	NA
56.7	Internal electric source	Piezoelectric	C
56.8	Indicators	Not used	NA
56.10	- Command operative means voltage fastening Movement limitation	Buttons of discharge insulated from high voltage contact	C
56.11	a) Operating voltage limitation b) Mechanical strenght c) Involuntary operation d) liquid protection e) Connection cords	-	NA
Mains connected parts, components and disposition (art.57)			
57.1	Visual inspections and tests: - mains separation:	 --	NA
57.2	- appliance inlets and sockets	--	NA
57.3	- supply cord	--	NA
57.4	- supply cords connection Traction: Torsion:. Sheath moving: conductors moving:	--	NA
57.5	Flexion: radius of curvature - mains connection devices and mains connected parts conductors.	--	NA
57.6	Fusibles and maximum current protector devices	--	NA
57.8	Conductors of the mains connected part	--	NA
57.9 57.9.1 57.9.2 57.9.4	- supply transformers: overheating: a)short-circuit: b)overload: Electric strenght: a)between windings and between windings and screen/core (see tests art.20) b)between the turns and between the windings layers: construction:	--	NA
57.10	Clearances and creepage distances: - A-a1: between energized parts and safety earthed accessible parts. - A-f mains conected parts at different polarities - B-a mains connected parts and applied part. - B-c applied parts and parts that are mains separate	Measured (mm) limit (mm) -- -- -- --	C

ref. Norm	*Prescription*	*Observed*	*Outcome*
	with only fundamental insulation. - B-d applied parts- enclosure	cr: >30 11 cl: >30 6	
	Costruzione e disposizione (art.59)		
59.1	Visual inspections: - internal conductors	--	NA
59.2	- Insulation test on thermoplastic enclosure material at 75°:	Plastic enclosure; test with 75°C for 1hour: 1mm (limit: 2mm)	
59.3	- protection against overcurrent and overvoltages:	--	NA
59.4	- Oil tanks	--	NA

5. TEST PROCEDURES AND CONDITIONS

Tests and controls executed on the device indicated on paragraph 2 have been performed on no. 1 example, in the same conditions in which it was prepared by the customer (in an use conform configuration) in the premises of the laboratory ELETTRA s.r.l. ELETTROLAB, located in Matteucci, 10 50041 Calenzano (FI). Tests have been performed in the followings dates: 04/08/08÷ 21/08/08. In the next sections, to guarantee the results reproducibility, they are riported the details of test modalities for some instrumental tests.

5.1 Test:	**Heating effect**	Art.	**42**
Test conditions:	Device placed on insulated support. Running cycle: Continuous switch Ambient temperature: 25°C Surface temperatures obtained with termocouples type J connected with a data acquisition instrument; windings temperatures obtained with resistance variation method.		
Instruments	Multichannel acquisition system HP34970 sn US37028187 Next calibration: 28/07/2009		
Results	Temperatures inside limits		

Parts	Measured value	Limits
Parts accessible without tools:	27	85
Accessible surfaces if hold in hand:	29	65
Buttons:	28	55
Parts in contact with the patient for a few:	27	50

Outcome	**Pass**

5.2 Test:	**Leakage current**	Art.	**19**
Test conditions:	Device placed on insulated support. Running cycle: Continuous switch and stand-by Measurement executed in normal operation condition and repeated before and after conditioning in humid chamber for 48h at 30°C with U.R. 95%.		
Instruments	Multi function instrument for safety tests on medical electrical equipment METRON QA90 sn 11162 Next calibration: 09/04/2009 Climatic chamber Perani mod AC520 sn 11124 Next calibration: 07/07/2009		

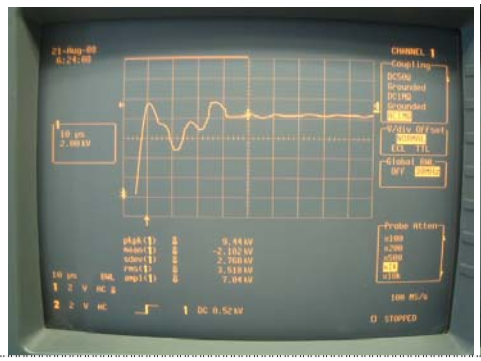
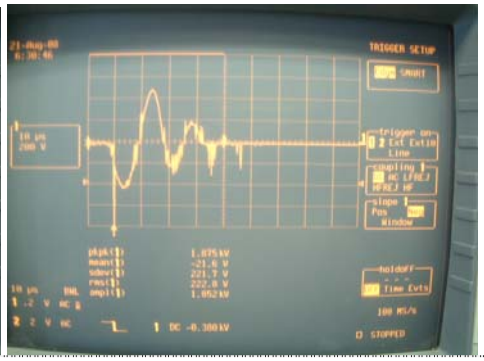
Results

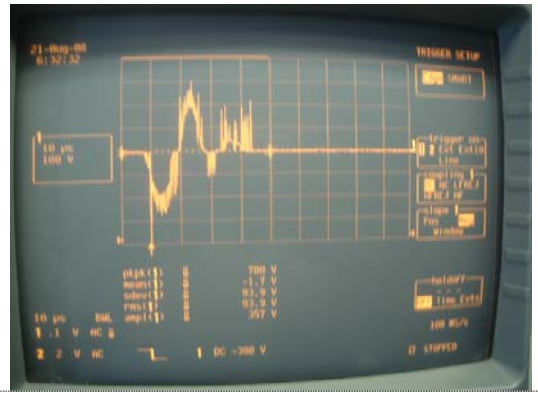
Leakage current in the enclosure			
Measured		Limit	
Normal conditions	Single fault	Normal conditions	Single fault
0µA	--	0,1mA	0,5mA
Leakage current in the patient			
Measured		Limit	
Normal conditions	Single fault	Normal conditions	Single fault
0,0µA ac 0,0µA dc	-- 2,9 µA ac	0,1mA ac 0,01mA dc	0,5mA ac 0,05mA dc 5mA (mains on app. parts)

Photo of the test	 
Outcome	**Pass**

5.3 Test:	**Electric strenght**	Art.	**20**
Test conditions:	Device not supplyed, placed on insulating support. Running cycle: device out; test repeated after hygroscopic preconditioning. Application for 1 minute of a sinusoidal voltage at 50 Hz of the following values and between the following parts: - Patient electrode – enclosure: 5320V This voltage was determined by dividing the maximum rated voltage per 2.√2 according to note 2 of cl. 20.3		
Instruments	Multitest device VITEK V63 sn 20066 Next calibration: 09/05/2009		

Results	No air or surface flashovers
Outcome	**Pass**

5.4 Test:	**Precision of output values and protection against dangerous outputs**	Art.	**50-51**
Test conditions:	Device placed on insulated support. Running cycle: Continuous with switch Outputs connected to loads 2000Ω 1000Ω, 500Ω Measurement of output with oscilloscope		
Instruments	Oscilloscope Le Croy 9310AM sn 93104781 Next calibration: 13/09/2008		
Results	Measured values less than limits: - No load voltage: 9,44kV ; - Voltage with 1000Ω load: 700V peak-peak; 93,5V rms - Voltage with 2000Ω load: 1875V peak-peak; 222V rms - Voltage with 500Ω: 481V peak-peak; 36V rms – 72mA (limit 100mA)		
Diagram of voltage:	 		

	
Outcome	**Pass**

6. CONCLUSIONS

The evaluations pointed out in the last paragraph consent to express a result of conformity of the device to the Standard CEI EN 60601-1 and next versions A1, A11 and A12 and version A2 and to the standard EN 60601-2-10